



Implants Technologies Ltd.

K101014

**510(k) Summary:**

OCT 21 2010

**Bond Bone™**

**Company Name:** MIS Implants Technologies Ltd.  
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Telephone: +972-4-901-6800  
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**Establishment Registration Number:** 3004203816

**Contact Name:** Iman Khorshid  
VP Quality & Regulatory Affairs  
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**Date prepared:** July 30, 2010

**Trade Name:** Bond Bone™

**Classification name:** Bone Grafting Materials

**Common/usual name:** Bone Grafting Materials, Synthetic

**Product Code:** LYC

**Regulation No.:** 872.3930

**Class:** II

**Classification Panel:** Dental Products Panel

**Predicate Device:**

Bond Bone™ from Augma Biomaterials Ltd., Usishkin 8, Netanya 42273, Israel cleared under 510(k) No. K083858.

**Description of the device:**

Bond Bone™ is a synthetic osteoconductive, bioresorbable bone grafting material composed of biphasic calcium sulfate in granulated powder form, intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. When mixed with saline, Bond Bone forms a paste and hardens via a cementitious reaction. The product is provided sterile and for single patient use.

**Indications for Use:**

Bond Bone™ is indicated for use in the following ways: by itself in bone regenerative techniques, mixed with other suitable bone filling agents to prevent particle migration in an osseous defect, and to provide a resorbable barrier over other bone graft material.

**Substantial Equivalence:**

Bond Bone™ has the same intended use as **Bond Bone™ from Augma Biomaterials Ltd., Usishkin 8, Netanya 42273, Israel cleared under 510(k) No. K083858**, and has same performance characteristics. Bond Bone™ is therefore substantially equivalent to the predicate device.

**Performance testing:**

Bond Bone™ has been tested for a number of chemical and physical characteristics: chemical composition, phase composition, trace of impurities, density and porosity, particle size, morphology, setting time and reaction temperature, compressive strength and elastic modulus, pH analysis and dissolution rate.

All these characteristics are equivalent to those of the predicate device.

**Conclusion:**

The evaluation of Bond Bone™ does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Ms. Iman Khorshid  
Vice President Quality & Regulatory Affairs  
MIS Implants Technologies Limited  
P.O. Box 7  
Bar Lev Industrial Park  
Israel 20156

OCT 21 2010

Re: K101014  
Trade/Device Name: Bond Bone<sup>TM</sup>  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: LYC  
Dated: September 7, 2010  
Received: September 9, 2010

Dear Ms. Khorshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



Implants Technologies Ltd.

OCT 21 2010

### INDICATIONS FOR USE

510(k) Number (if known):

K101014

Device Name:

Bond Bone™

Indications for Use:

Bond Bone™ is indicated for use in the following ways: by itself in bone regenerative techniques, mixed with other suitable bone filling agents to prevent particle migration in an osseous defect, and to provide a resorbable barrier over other bone graft material.

Prescription Use X OR  
(Part 21 CFR 801 Subpart D)

Over the Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:

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